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June 15, 2020

Via ECF

The Honorable Joel Schneider
United States Magistrate Judge
USDC, DISTRICT OF NEW JERSEY
Mitchell H. Cohen Building & U.S. Courthouse
4th & Cooper Streets
Camden, NJ 08101

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*
USDC, District of New Jersey, No. 1:19-md-2875-RBK-JS

Dear Judge Schneider:

The Manufacturer Defendants submit the following Reply in Support of the Defendants' Motion to Modify the ESI Search Terms.

I. Mylan

Plaintiffs' assertion that Mylan has failed to show good cause for modification of the ESI Search Terms contained in the Court's December 23, 2019 Order, Dkt. 328 (the "Original Search Terms"), can be distilled into three main arguments, each of which is demonstrably false.¹

First, Plaintiffs accuse Mylan of failing to timely meet and confer with Plaintiffs regarding the proposed changes to the Original Search Terms. In reality, it was Plaintiffs—not Mylan—who refused to engage in a meaningful dialogue from the time Mylan submitted its counterproposal in mid-March until less than two weeks ago, and only then at this Court's urging and at Mylan's request. The Court should not reward Plaintiffs' gamesmanship by denying Mylan's application for much-needed modifications to the Original Search Terms.

Second, Plaintiffs suggest Mylan has violated two Orders—the ESI Protocol and the December 2019 Order—and that Mylan cannot show good cause as a result. Plaintiffs, however, mischaracterize these Orders in an effort to both rewrite history and confuse the issues. Their flawed reading of these Orders should be disregarded.

¹ Plaintiffs also incorporate their lengthy May 11, 2020 letter by reference. Dkt. 459-1. Plaintiffs attributed many of the arguments contained in that letter to their eDiscovery consultant, Jonathan Jaffe. In order to rebut the positions taken by Mr. Jaffe, Mylan has enlisted its eDiscovery consultants, Daniel Coppola and Elizabeth Erickson of Consilio, to assist in the preparation of a point-by-point rebuttal, which is enclosed as Appendix-1.

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Third, Plaintiffs assert that Mylan has failed to explain why its proposed revisions to the Original Search Terms are necessary. Plaintiffs, however, ignore the low prevalence of responsive documents revealed by Mylan's document sampling. The purpose of compiling ESI search terms is to narrow the universe of documents that must be collected and reviewed by counsel prior to production. In essence, search terms are used to increase the prevalence of responsive documents in a collection, to reduce the time it takes to review and produce documents, and to curtail unnecessary costs associated therewith. The search terms at issue here capture millions of documents, but on average only 6% of those documents are responsive. As a result, the Original Search Terms do not serve their intended purpose. Mylan has shown good cause for modification of the Original ESI Search Terms, and this Court should adopt the revisions proposed by Mylan.

A. Plaintiffs only recently began to meet-and-confer with Mylan in good faith.

As the Court is aware, only days after the Court entered the December 23 Order setting the Original Search Terms and the ESI custodians, Mylan went to work collecting custodial data and analyzing the search terms. As soon as Mylan gathered initial data, Mylan reached out to Plaintiffs to initiate a meet-and-confer, and ultimately advised Plaintiffs that significant revisions to the search terms would be needed.

Based on the time-intensive analysis and testing that followed, on March 19, 2020, Mylan submitted a revised version of the Original Search Terms contained in this Court's December 23, 2020 Order (the "Revised Search Terms"). Thereafter, Plaintiffs made various requests of Mylan for additional information related to the Revised Search Terms, which Mylan provided. But it was not until Plaintiffs submitted their May 11, 2020 letter, attached as Exhibit A to Plaintiffs' Response Brief, Dkt. 459-1, that Plaintiffs took any position whatsoever on the substance of Mylan's proposal.² As a result, the parties lost nearly two months, during which time Plaintiffs could and should have been engaged with Mylan negotiating necessary revisions to the Original Search Terms. Rather than participate in this iterative process in good faith, Plaintiffs refused to negotiate, leaving Mylan with no choice but to seek blanket relief from the Court.

It was not until the Court's recent suggestion that the parties meet and confer to determine whether compromise was possible, and after Mylan reached out to Plaintiffs and communicated its continued willingness to engage in negotiations, that Plaintiffs finally agreed to work with Mylan to revise the Original Search Terms. Although the parties have not been able to reach an agreement, these recent discussions have been both cooperative and productive. Plaintiffs cannot justify why they did not engage in these same discussions months ago when Mylan first proposed the Revised Search Terms. Indeed, Mylan never presented the Revised Search Terms as a "take it or leave it" proposition. Rather, Mylan always viewed its proposal as a starting point for a collaborative discussion with Plaintiffs, which is precisely what the December 23 Order requires.

² The token concessions proposed by Plaintiffs on May 11 did nothing to reduce the volume of hits or address the low prevalence of responsive documents. Although Plaintiffs characterize these as "significant modifications," in reality Plaintiffs agreed to revise less than ten of the several hundred primary search terms.

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On the one hand, Plaintiffs refused to negotiate with Mylan until *after* this Court directed the parties to meet-and-confer on May 29, 2020; yet, at the same time, Plaintiffs accuse Mylan of failing to engage in the process outlined in the Court's December 23 Order, ignoring that Mylan submitted the Revised Search Terms *nearly three months ago*. To say that Plaintiffs are trying to have it both ways is an understatement. In order to reach meaningful compromise with Plaintiffs on this issue, both Mylan and Plaintiffs were required to act in good faith. The only reason why the discussions in which the parties are now engaged could not have occurred months ago is because Plaintiffs refused to participate. Indeed, Plaintiffs' decision not to negotiate in good faith supports Mylan's assertion that good cause exists to adopt the Revised Search Terms because Plaintiffs made it impossible for Mylan to engage in the iterative process contemplated by the December 2019 Order.

B. Plaintiffs mischaracterize this Court's prior discovery Orders.

Plaintiffs suggest Mylan has violated both the ESI Protocol, Dkt. 127, and the December 23, 2019 Order, and therefore there is no good cause for modification of the Original Search Terms. Plaintiffs have mischaracterized these Orders. First, the ESI Protocol has no bearing whatsoever on the outcome of the present dispute (apart from its requirement that the parties work together to refine ESI search terms). Second, Mylan has followed the process outlined in the Court's December 2019 Order regarding the ESI Search Terms. Plaintiffs have not.

The ESI Protocol governs the manner in which electronic information is to be *produced* during discovery in this litigation: "The Parties shall not produce exact duplicates of electronic documents stored in different locations. Each Party must globally de-duplicate identical ESI vertically within each custodian and horizontally across custodians[.]" Dkt. 127 at 9. The ESI Protocol *does not* mandate that the Defendants collect or analyze their own data in any particular way. So long as the ultimate production of documents conforms to the requirements of the ESI Protocol, then the Defendants have complied with that Order.

Plaintiffs, however, argue that Mylan "has failed to follow the ESI protocol and both vertically and horizontally de-duplicate documents and enable e-mail threading." Plaintiffs further assert that "Mylan's argument that it did not want to spend to [sic] necessary funds to do so does not hold any water in the face of a Court ordered ESI Protocol." Contrary to the Plaintiffs' assertion, nothing in the ESI Protocol requires Mylan to incur *millions of dollars* in costs to de-duplicate and thread emails where Mylan has also demonstrated that the vast majority of those emails are non-responsive and will never be produced to Plaintiffs. Indeed, Mylan would never have agreed to the ESI Protocol, which was negotiated by the parties, in the first instance if it required Mylan to process millions of demonstrably non-responsive documents. Thus, Plaintiffs' reliance on the ESI Protocol is a red herring.

Similarly, Plaintiffs also mischaracterize the Court's December 23, 2019 Order governing the search terms. Prior to the entry of this Order, the Defendants were not in a position to test search terms because the parties were still actively negotiating ESI custodians. Indeed, Mylan and Plaintiffs did not agree to a final list of custodians until December 17—less than a week before the Court entered its Order setting the Original Search Terms. Moreover, even if Mylan had gathered

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hit counts for a subset of agreed-to custodians prior to the entry of the December 2019 Order, this information would have been of only marginal value. Specifically, because the search terms cover various subjects (manufacturing, regulatory QA-testing, etc.), the results of any testing would have been skewed based upon the specific role of the custodian. For example, a custodian who is heavily involved in regulatory affairs, but has no role related to manufacturing or testing, may have a high volume of hits related to the “regulatory” search terms, but relatively few hits related to the “manufacturing” search terms. In isolation, Plaintiffs would have undoubtedly used this information to argue that the search terms were performing as anticipated. Only when applied across all 52 of Mylan’s ESI custodians does the full picture emerge. Thus, subsequent testing of the search terms across the entire custodial population, which was not finalized until the December 2019 Order, was always understood by the parties as both necessary and proper.

In recognition of this, the December 2019 Order details an “iterative process” according to which the parties are permitted to further refine the Original Search Terms based on hit counts, testing, and sampling of documents. As this process makes clear, neither party ever considered the Original Search Terms to be “final” or “set in stone.” Rather, the parties contemplated an ongoing, cooperative process by which problematic terms, or categories of terms, would be revised as data was collected and analyzed. Mylan undertook this process, and first reached out to Plaintiffs in mid-January alerting them that the Original Search Terms were capturing far more data than anticipated. During those initial discussions, Mylan made Plaintiffs aware that it would propose modifications to a number of the search terms.

Plaintiffs assert that, when Mylan proposed the Revised Search Terms, Mylan was somehow flouting the “iterative process” contemplated under the December 2019 Order. Plaintiffs’ argument ignores the plain text of that Order. Specifically, all that Mylan was required to do to initiate a meet-and-confer with Plaintiffs under the Order was to obtain hit counts and, in some instances, perform additional testing and sampling of the Search Terms. Mylan did this beginning in January and developed the Revised Search Terms in accordance with this process. To be sure, the Revised Search Terms constitute a significant modification to the Original Search Terms. In Mylan’s case, however, a significant revision is exactly what is necessary due to the high number of ESI custodians (52) and the significant volume of data being captured—***31% of all custodial emails, and nearly 70% of all custodial data.***

Even so, the Revised Search Terms maintain the overall framework of the Original Search Terms and do not amount to a “massive wholesale revision” or a “radical modification” of the Original Search Terms, as Plaintiffs misleadingly suggest. By characterizing the Revised Search Terms in this manner, Plaintiffs attempt to remove Mylan’s Revised Search Terms from the “iterative process” contemplated by the December 23 Order. To the contrary, Mylan has followed the Court-ordered process, as discussed in detail in the Defendants’ opening letter-brief.

Plaintiffs also argue that Mylan waited too long to raise an issue with the Original Search Terms in violation of the December 2019 Order. To the contrary, Mylan circulated the Revised Search Terms on March 19, 2020—more than 8 months prior to the current deadline to complete ESI discovery. A process cannot be “iterative” and ongoing if it must also be completed while discovery is in its infancy. Plaintiffs acknowledged this when they agreed to the protocol set forth

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in this Court's December Order, which encouraged a continuous meet-and-confer regarding the Original Search Terms. Moreover, Plaintiffs have represented to the Court that, even months after Mylan first made contact to begin the process of revising the Original Search Terms, they remain willing to confer with Defendants to refine the terms. The fact remains that Mylan has followed the process outlined by the December Order, and Plaintiffs' suggestions otherwise are merely an attempt to distract from the fundamental problems Mylan has identified with respect to the Original Search Terms.

C. Plaintiffs completely ignore the low prevalence of responsive documents.

Plaintiffs generally assert that Mylan has not offered adequate justification for the changes it proposed in the Revised Search Terms, and yet, Plaintiffs have not even attempted to address the issue at the heart of this dispute: the remarkably low prevalence of responsive documents being captured by the Original Search Terms. This low rate of responsiveness is at the forefront of Mylan's good cause argument to modify the Original Search Terms.

Mylan's initial document sampling indicated that up to **94%** of the documents captured by the Original Search Terms were **non-responsive**. Simply put, the search terms as presently constructed do almost nothing to shrink the universe of documents that must be processed and reviewed in order to produce those that are responsive. *See, e.g., Lawson v. Spirit Aerosystems, Inc.*, No. 18-1100, 2019 WL 1877159, at * 3 (D. Kan. April 26, 2019) (requiring modification of ESI search terms unless the responsive rate for the initial custodians was 85% or higher). Mylan emphasized this low responsive rate in the documents Mylan sampled to Plaintiffs in an effort to convince Plaintiffs of the need to meet and confer to revise the Original Search Terms. Defendants ZHP and Teva have likewise found a low rate of responsiveness based on the analysis of their own data.

Rather than address the substance of Mylan's data, Plaintiffs dwell on the process. Their hired consultant took the position that Mylan's sampling methodology was flawed and unreliable. Plaintiffs' consultant suggested an alternative methodology that Mylan should have used to determine the prevalence of responsive documents. Thereafter, Mylan adopted the very methodology Plaintiffs insisted would lead to statistically significant information. This second sample set more than doubled the number of sample documents Mylan reviewed as compared to the initial sample set. Tellingly, however, the results were the same. Once again, even using Plaintiffs' suggested methodology, 94% of the documents captured by the Original Search Terms were non-responsive. This not only confirmed that Mylan's initial sampling was adequate, but also eliminated any doubt that the Original Search Terms are capturing an unacceptably high proportion of irrelevant documents.

In response, Plaintiffs have not even acknowledged that Mylan performed additional sampling, nor do they bother arguing that 94% non-responsiveness is reasonable. Plaintiffs' silence with regard to this crucial issue speaks volumes. At bottom, no one disputes that the Original Search Terms are overly broad; no one disputes that a 6% responsiveness rate is wildly inappropriate; and no one disputes that, with respect to a company like Mylan that markets

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hundreds of products, it defies logic and commonsense that the Original Search Terms are capturing 31% of all emails sent and received over the course of nearly a decade. Despite this, Plaintiffs reject the use of common techniques, such as reasonable proximity limiters used in place of the “AND” connector, which would help to ensure that there is a nexus between a primary term and a modifier term. *See, e.g., Cty. of Cook v. Bank of Am. Corp.*, No. 14 C 2280, 2019 U.S. Dist. LEXIS 182379, at *20-23, 2019 WL 5393997 (N.D. Ill. Oct. 22, 2019) (replacing the “AND” connector between primary terms and modifier terms with a “within 60” proximity limiter in order to exclude “voluminous documents that have nothing to do with the facts of this case . . .”).

Rule 26 was amended in 2015 to reemphasize the role of proportionality in defining the scope of discovery under the Federal Rules of Civil Procedure: “The 2015 amendments were intended, at least in part, to encourage judges to be more aggressive in policing discovery overreaching. *Homeward Residential, Inc. v. Sand Canyon Corp.*, No. 12CV5067JFKJLC, 2017 WL 4676806, at *7 (S.D.N.Y. Oct. 17, 2017) (internal citations and quotations omitted. Indeed, “[p]roportionality and relevance are conjoined concepts; the greater the relevance of the information in issue, the less likely its discovery will be found to be disproportionate.” *Id.* (internal citations and quotations omitted); *see also Miller UK Ltd. v. Caterpillar, Inc.*, 17 F. Supp. 3d 711, 721 (N.D. Ill. 2014) (stating that discovery was never “intended to be an excursion ticket to an unlimited exploration of every conceivable matter that captures an attorney's interest.”).

As applied to the present dispute, these principles weigh heavily in favor of adopting Mylan’s proposed modifications to the Search Terms. It is notable that Mylan has agreed to all of the Original Search Terms that relate specifically to the alleged impurity in valsartan API. For example, Mylan has agreed to run terms such as *NDEA*, *NDMA*, *nitra*, *nitrite*, *nitrosa*, *nitroso*, *NMBA*, *trosamine*, gene /3 mutat*, solvent /5 contammin*, and many others, as standalone terms, without modification, across all custodians. Further, Mylan has engaged in core discovery, which resulted in production of the relevant Drug Master File, ANDA files, and FDA recall correspondence. Given both the quantity and the quality of the information Mylan has already produced, or has agreed to produce, requiring Mylan to also collect and review 70% of all custodial email generated over the past decade is not proportional to the needs of this case.

This Court has repeatedly assured the parties that all orders are subject to modification on a showing of good cause. Mylan has done so. Accordingly, Mylan respectfully requests that this Court modify its December 23, 2019 Order and adopt the Revised Search Terms in their entirety as to Mylan.

II. Teva

The Teva Defendants acknowledge that during their initial meet and confer in February the parties were able to come to a number of agreements on modifications to the Court approved search terms. However, during subsequent rounds of internal revisions, it became apparent that using these limited revisions the Original Search Terms were still returning a huge volume of false positives. Given the wide range of products worked on by the various custodians utilized by the Teva Defendants for testing the search terms, results which would require promotion to the review space of more than 40% of the documents contained in these custodians’ emails, demonstrated not

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only that these terms as drafted are plainly overbroad, but that more radical modifications to the search terms were needed. Accordingly, the Teva Defendants raised this issue to Plaintiffs and the Court during both the April 15, 2020 teleconference, 4/15/20 Trans. at 16-17, and ahead of the April 29, 2020 CMC, Dkt. 419 at 5.

On April 24, 2020, the Teva Defendants joined in the Manufacturer Defendants' counterproposal, which utilized various limitations to significantly reduce the number of hits. Notably, the Teva Defendants' random sample review, which Plaintiffs do not address at all in their response, showed a markedly higher rate of responsive documents found in the random sample pulled from the counterproposal search results rather than the results using the original search terms – 14.8% vs. 1.3%. This analysis suggests that virtually no responsive documents will be lost if the counterproposal terms are utilized.

Rather than address the crux of the issue—an overbroad search returning terabytes of data worth of overwhelmingly non-responsive documents—Plaintiffs again complain about the process and make several misleading statements about the results of the Teva Defendants' initial test searches. For example, the use of the phrase “Teva” is not “responsible for well over one million documents with families in Teva’s hit report,” and the application of economic terms across Teva’s custodians did not result in “over two million documents with families” being identified as requiring review. Dkt. 459, at 10. As explained to Plaintiffs’ counsel during the parties’ most recent meet and confer, less than 30,000 unique documents—out of 2.4 million—were included in the hit counts solely as a result of including the term “Teva.”

The Teva Defendants subsequently ran an updated hit count correcting these issues and implementing additional modifications agreed to by Plaintiffs, and while there has been a reduction in the overall volume, it has not meaningfully altered the reality that the current search terms create a large and unnecessary review burden. The Teva Defendants intend to continue negotiating with Plaintiffs to determine if the parties can reach agreement on additional limitations to the search terms, and this dialogue is ongoing.

III. ZHP

As set forth below, the Parties have agreed to continue to negotiate in order to refine the ESI search terms to be applied by the ZHP Parties.

Due to COVID-19, the ZHP Parties were prevented from collecting custodial and non-custodial ESI and hardcopy information from their respective facilities until mid-April, 2020. Since then, they have collected more than seven terabytes of ESI and hundreds of thousands more hardcopy pages. Due to the unquestionable overbreadth of the Original Search Terms approved by the Court in December 2019, the vast majority of the information that must be reviewed is not responsive to Plaintiffs’ court-approved document requests. Preliminary analysis shows less than a 7% responsiveness rate.

As set forth in Defendants’ opening brief, based on an agreement between the Parties, the Court entered an Order on December 23, 2019 that provides for the Parties to meet and confer to

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narrow the list of search terms based on sampling and testing of the terms. Indeed, as the Court has previously noted, neither Party should want to incur the cost of reviewing non-responsive information. Since beginning their collection of ESI and hardcopy information in April, the ZHP Parties and Plaintiffs have been meeting and conferring pursuant to the December 2019 Order. After Defendants filed their opening brief, Plaintiffs agreed with the ZHP Parties to continue those negotiations beyond the filing of this Reply brief in order to effectuate the iterative refining of the search terms as contemplated in the December 2019 Order. As Plaintiffs concede, these “modification negotiations are supposed to be an iterative process where proposed modifications are tested, reports generated, reviewed, subject to sampling where needed, and then additional changes tested based upon those results . . .” Pls. Ltr. Br. at 7, Dkt. No. 459.

Given the overwhelming amount of information the ZHP Parties have collected, the ongoing negotiations between the ZHP Parties and Plaintiffs are expected to include, among other things, sharing hit count information related to the data currently being processed in China, sampling the search terms on the U.S. data and China data to further refine specific terms, and identifying “false positives” during the course of the review. Concurrent with those negotiations, the ZHP Parties will be incurring the expense of reviewing the information they have collected, which will necessarily include the review of non-responsive information, so as to be in the best position to satisfy the deadlines for production established by the Court in April, before the ZHP Parties had even begun to collect their ESI and hardcopy information.

Recognizing that it would take *hundreds* of contract attorneys, at a cost of many millions of dollars, to review the seven-plus terabytes of collected information in order for the ZHP Parties to meet the Court’s production deadlines, the ZHP Parties are dependent upon Plaintiffs to negotiate in good faith and to make real concessions in narrowing the search terms list so as to meaningfully reduce the volume of information the ZHP Parties have to review and produce over the next six months. Preliminary analysis suggests that the search term modifications that Plaintiffs have agreed to thus far will decrease the number of documents to be reviewed by *only 27%* and will increase the responsiveness rate from under 7% to *just about 11%*. While the preliminary results reflect some progress, clearly far greater modifications are necessary if the ZHP Parties are to be expected to satisfy the Court’s production deadlines, and in order to avoid the ZHP Parties having to retain hundreds of contract attorneys and expend millions of dollars to review nonresponsive documents.

Given the onerous burden on the ZHP Parties in light of the breadth of the Original Search Term and the Court-ordered production schedule, the ZHP Parties will promptly raise with the Court issues that cannot be resolved through the ongoing negotiations.³


³ Plaintiffs appear to seek their own relief from the Court in the form of an order “that any future request by any Defendant for a Court order modifying search terms show not just good cause for the modification, but also specifically show that the particular Defendant could not have brought such request to the Court as part of this briefing.” Pls. Ltr. at 15, Dkt. No. 459. Plaintiffs’ request should be denied because the relief Plaintiffs seek is contrary to the agreed-upon meet and confer procedure set forth in both the December 2019 Order and the ESI Protocol—i.e., the iterative process that Plaintiffs acknowledge in their brief is part of their agreement with ZHP. Moreover, given the timing of the ZHP Parties’ collection of ESI and hardcopy information in light of COVID-19, which was delayed for “good cause,” it would be unfairly prejudicial to prevent the ZHP Parties from raising issues about their ESI and hardcopy

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Clem C. Trischler". The signature is fluid and cursive, with the first name "Clem" and last name "Trischler" clearly distinguishable.

Clem C. Trischler

c: All Counsel of Record (via ECF service)

information that cannot be resolved with Plaintiffs. Indeed, granting Plaintiffs' request would give Plaintiffs an incentive to be restrictive and recalcitrant in their negotiations with the ZHP Parties.